BlueCross BlueShield of Alabama

**Name of Blue Advantage Policy:**

# Suprachoroidal Delivery of Pharmacological Agents

Policy #: 312
Latest Review Date: February 2025
Category: Vision

## BACKGROUND:

***Blue Advantage*** *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

**Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare*** *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

## POLICY:

**Effective for dates of service on and after March 1, 2022:**

**Blue Advantage** will treat **suprachoroidal delivery of a pharmacologic agent** as a **covered benefit** for use with XIPERE™ (triamcinolone acetonide injectable suspension).

**Blue Advantage** will treat **suprachoroidal delivery of a pharmacologic agent** as a **non-covered benefit** and as **investigational** in all other situations.

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**Effective for dates of service prior to March 1, 2022:**

**Blue Advantage** will treat **suprachoroidal delivery of a pharmacologic agent** as a **non-covered benefit** and as **investigational**.

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## DESCRIPTION OF PROCEDURE OR SERVICE:

The delivery of pharmacologic agents to the suprachoroidal space has been investigated for the treatment of posterior eye segment disease. Two of the most posterior eye segment diseases are age-related macular degeneration and diabetic neuropathy. The posterior eye segment structures included the vitreous humor, retina, choroid, macula, and optic nerve.

The suprachoroidal delivery of a pharmacologic agent method uses a microcannula system that combines a drug delivery channel with a fiber optic light source for localization of the cannula tip. There are identified advantages and risks associated with this drug delivery method. One potential advantage of suprachoroidal injection is the ability to minimize systemic side effects while delivering high local tissue levels of drugs. A potential risk associated with utilizing this drug delivery method is the possibility of localized tissue damage caused by the microcannula.

There are various methods of invasive and noninvasive delivery of ocular medications. Some examples of invasive drug administration to intraocular cavities include suprachoroidal injections, intravitreal surgery, intravitreal injections, intracameral surgery, subretinal injections, and intracameral injections. Some examples of invasive periocular and scleral modes of drug administration include intrascleral surgery, episcleral surgery, periocular injections, subconjunctival injections, and transscleral diffusion from controlled release systems. There are several noninvasive method choices, such as topical administration on the eye, systemic administration (e.g. intravenous infusion or injection), and oral delivery. It is important to choose the delivery method that will most positively affect the net health outcomes of the individuals with minimal risk of adverse effects.

The most widely used method of ocular drug delivery is topical or systemic. Topical application has remained the most preferred delivery route due to ease of administration. Topical application is useful in the treatment of disorders affecting the anterior segment of the eye. Although topical and systemic routes are convenient, they lack bioavailability and can fail to deliver therapeutic levels of drugs to the retina and posterior segment structures which has prompted exploration of alternative routes of ocular drug administration.

## KEY POINTS:

This policy has been updated with a review of literature performed through March 22, 2024.

**Summary of Evidence**

There is inadequate evidence regarding the clinical utility of suprachoroidal injection of pharmacologic agents for the treatment of any ophthalmologic condition. Clinical outcome studies published in peer-reviewed medical literature are needed to determine the value of this drug delivery method in the management of individuals with diseases of the posterior segment of the eye. There is a paucity of well-designed clinical trials and scientific evidence to validate that this technology improves net health outcomes and is, therefore, considered investigational.

The drug, XIPERE® (triamcinolone acetonide), is indicated for use in the treatment of macular edema associated with uveitis. This drug is only available in SCS (suprachoroidal space) injectable form. When the drug is appropriate for use, the suprachoroidal injection of a pharmacologic agent is also deemed appropriate.

**Practice Guidelines and Position Statements**

No guidelines or statements were identified.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

## KEY WORDS:

Suprachoroidal delivery system, iTrack™, suprachoroidal delivery of pharmacological agents, SCS Microinjector®, Xipere®

## APPROVED BY GOVERNING BODIES:

The iScience Surgical Ophthalmic Microcannula, or iTRACK™, is a flexible microcannula designed to allow atraumatic cannulation of spaces in the eye such as the anterior chamber and posterior segment, for infusion and aspiration of fluids during surgery, including saline and viscoelastics. The microcannula incorporates an optical fiber to allow transmission of light to the microcannula tip for surgical illumination and guidance. The iScience Surgical Ophthalmic Microcannula is indicated for fluid infusion and aspiration, as well as illumination, during surgery. This device received 501(k) clearance from the U.S. FDA in 2004.

XIPERE® is administered with a SCS Microinjector®. XIPERE® is a sterile, preservative-free, injectable suspension of triamcinolone acetonide, a synthetic corticosteroid for use with the SCS

Microinjector®. The SCS Microinjector® is a piston syringe and a needle approximately 1 mm in length (900-µm and 1100-µm needles are included) for conducting the suprachoroidal injection. XIPERE® received clearance from the FDA on October 22, 2021.

## BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

## CURRENT CODING:

**CPT Codes**

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| 67516 | Suprachoroidal space injection of pharmacologic agent (separate procedure, **Effective 01/01/24**) |

**PREVIOUS CODING:**

**CPT Codes**

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| 0465T | Suprachoroidal injection of a pharmacologic agent (does not include supply of medication, **Deleted 12/31/23**) |

## REFERENCES:


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## POLICY HISTORY:

Adopted for Blue Advantage, January 2008
Available for comment January 9-February 22, 2008
Medical Policy Group, December 2008
Medical Policy Group, December 2009
Medical Policy Group, December 2010
Medical Policy Group, October 2011
Medical Policy Group, December 2013
Medical Policy Group, January 2014
Medical Policy Group, February 2015
Medical Policy Group, November 2019
Medical Policy Group, January 2021
Medical Policy Group, January 2022: Reviewed by consensus. References added. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, February 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy. Created previous coding section. Moved CPT code 67299 from current coding section to previous coding section.
Medical Policy Group, February 2022: Policy statement updated- "suprachoroidal delivery of a pharmacologic agent may be considered medically necessary for use with XIPERE™ (triamcinolone acetonide injectable suspension)" effective for dates of service on or after March 1, 2022.
Medical Policy Group, February 2023: Reviewed by consensus. No new published peer-reviewed literature is available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: 2024 Annual Coding Update- Added CPT code 67516 to the Current Coding section. Moved CPT code 0465T from Current Coding section to include it in the Previous Coding section.

UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, March 2024: Reviewed by consensus. No new published peer-reviewed literature is available that would alter the coverage statement in this policy.
UM Committee, March 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, February 2025: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

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